SECTION 5
510(k) SUMMARY (CONT.) page 1 of 3

510(k) Notification K 07 3265

GENERAL INFORMATION

Applicant:

Apieron, Inc.
155 Jefferson Drive
Menlo Park, CA 94025
USA
Phone: 650-454-8127
FAX: 650-454-8190

MAR 14 2008

Contact Person:

Richard Lotti
President & CEO
Apieron, Inc.
155 Jefferson Drive
Menlo Park, CA 94025
USA
Phone: 650-454-8127
FAX: 650-454-8190

Date Prepared: November 16, 2007

DEVICE INFORMATION

The Apieron INSIGHT™ eNO System consists of a Monitor, a single-use disposable Sensor Cartridge and other disposable test supplies. The Monitor contains the measurement and breath sampling hardware and provides a user-friendly interface to guide the operator through the test sequence and guide the patient through the breath sampling maneuver. The disposable Sensor Cartridge contains a Biosensor that changes its optical transmission properties when it reacts with the nitric oxide in the breath sample. The Apieron INSIGHT eNO System is transportable, operated by an AC outlet and designed for use with the disposable Sensor Cartridge.

Classification:

Breath Nitric Oxide Test System, 21 CFR§862.3080, Class II (special controls). The special control is FDA's guidance entitled "Class II Special Controls Guidance Document: Breath Nitric Oxide Test System".

Product Code:

MXA

Trade Name:

Apieron INSIGHT™ eNO System

Generic/Common Name:

Breath Nitric Oxide Test System

SECTION 5
510(k) SUMMARY (CONT.)

page 2 of 3

PREDICATE DEVICE

Aerocrine NIOX® System

INTENDED USE

The intended use of the Apieron INSIGHT™ eNO System is to quantitatively measure exhaled nitric oxide (eNO) in expired human breath as a marker of inflammation in persons with asthma. Measurement of eNO in expired human breath by the Apieron INSIGHT eNO System is a non-invasive, simple and safe method to measure a decrease in eNO in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of the therapeutic effects in patients with elevated eNO levels. The Apieron INSIGHT eNO System is suitable for use in children ages 8 to 17 years of age, and in adults 18 years of age and older. eNO measurements, as an adjunct to established clinical assessments, provide the physician an objective marker to evaluate the patient's response to anti-inflammatory therapy. The Apieron INSIGHT eNO System can be used by trained operators in a physician's office laboratory setting. The Apieron INSIGHT eNO System should not be used in critical care, emergency care or in anesthesiology.

PRODUCT DESCRIPTION

The Apieron INSIGHT™ eNO System consists of a Monitor, a single-use disposable Sensor Cartridge and other disposable test supplies. The Monitor contains the measurement and breath sampling hardware and provides a user-friendly interface to guide the operator through the test sequence and guide the patient through the breath sampling maneuver. The disposable Sensor Cartridge contains a Biosensor that changes its optical transmission properties when it reacts with the nitric oxide in the breath sample. The System is transportable, operated by an AC outlet and designed for use with the disposable Sensor Cartridge.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate device is substantially equivalent to the proposed indications for use for the Apieron INSIGHT eNO System. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the Apieron INSIGHT eNO System is substantially equivalent to the predicate device.

SECTION 5
510(k) SUMMARY (CONT.)

page 3 of 3

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench and clinical testing was conducted on the Apieron eNO System to support a determination of substantial equivalence to the predicate device.

SUMMARY

The Apieron INSIGHT eNO System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 14 2008

Apieron Inc.
c/o Mr. Richard Lotti
President & CEO
155 Jefferson Drive
Menlo Park, CA 94025

Re: k073265
Trade Name: Apieron INSIGHT™ eNO System
Regulation Number: 21 CFR §862.3080
Regulation Name: Breath nitric oxide test system.
Regulatory Class: Class II
Product Code: MXA
Dated: March 05, 2008
Received: March 06, 2008

Dear Mr. Lotti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K073265

Device Name: Apieron INSIGHT™ eNO System

Indications For Use:

The intended use of the Apieron INSIGHT™ eNO System is to quantitatively measure exhaled nitric oxide (eNO) in expired human breath as a marker of inflammation in persons with asthma. Measurement of eNO in expired human breath by the Apieron INSIGHT eNO System is a non-invasive, simple and safe method to measure a decrease in eNO in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of the therapeutic effects in patients with elevated eNO levels. The Apieron INSIGHT eNO System is suitable for use in children ages 8 to 17 years of age, and in adults 18 years of age and older. eNO measurements, as an adjunct to established clinical assessments, provide the physician an objective marker to evaluate the patient's response to anti-inflammatory therapy. The Apieron INSIGHT eNO System can be used by trained operators in a physician's office laboratory setting. The Apieron INSIGHT eNO System should not be used in critical care, emergency care or in anesthesiology.

Prescription Use _X_	And/Or	Over the Counter Use _____
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety